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Premarket Notification [510(k)] Summary

1. Submitter Name, Address, and Date of Preparation

Brian J. Young
Sr. Regulatory Affairs Manager
Weck Closure Systems
One Weck Drive
Research Triangle Park, NC 27709

Telephone: (919) 361-4041
Date Prepared: December 13, 2000

2. Name of the Device, Common, Proprietary (if known), and Classification

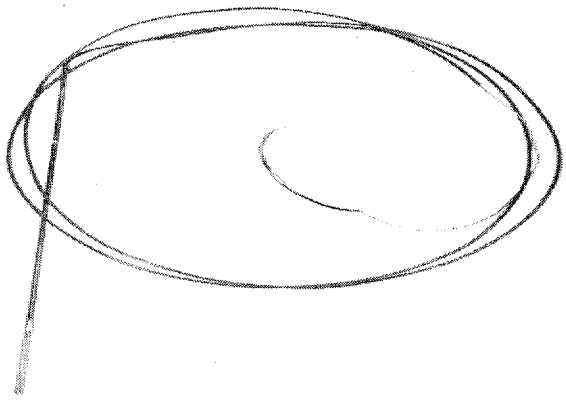
Classification Name:	Temporary pacemaker electrode
Common Name:	Temporary epicardial pacing wire
Proprietary Name:	Weck Cardiac Pacing Wires

3. Identification of the legally marketed device to which the submitter claims equivalence

Weck Temporary Cardiac Pacing Wires are substantially equivalent to Weck's preamendment Temporary Cardiac Electrodes, Ethicon TPW 32 and TPW 92 pacing wires, and Medtronic Model 6500 and 6491 temporary pacing wires.

4. Description of the Device

Weck cardiac pacing wires consist of a small curved stainless steel needle attached to fluoropolymer coated stainless steel braided wire which is attached on the opposite end to a Keith or Milner breakaway needle (see picture below). The wire is bare at the distal end to allow conduction of pacing signals to the heart. This is a standard temporary epicardial pacing wire design.



There are three design variations included in this submission that are offered as a convenience to the user:

1. Color coding – White and orange color coding of the insulation allows the user to differentiate between atrial and ventricular wires after chest closure.
2. Heart needle – Three heart needle sizes are intended to allow for variations in physiology between patients. Another variation has no curved heart needle for surgeons who prefer to suture the wire to the epicardium rather than implanting it.
3. Retention feature – A "wing" version wire is formed by peeling back the insulation in three places, 120° apart, for a distance of ½" near the curved heart needle. The "wing" is intended as a convenience feature to provide a suture-free method of securing the electrode to the heart.

5. Intended Use of the Device

Weck Cardiac Pacing Wires are intended for use in temporary cardiac pacing following cardiac surgery in adult and pediatric patients.

6. Summary of Technological Characteristics

The technological characteristics of the modified device are the same as or equivalent to the predicate device.

7. Performance Data

Weck confirmed biocompatibility of the wires according to FDA G95-1 / ISO 10993-1 requirements.

Weck evaluated each characteristic of the wires important to proper functioning and confirmed that each of the wires is equivalent and performs acceptably with respect to: (1) electrical continuity; (2) strength of the needle swages and ability to withstand tensile forces that may be encountered during use; (3) corrosion resistance; (4) heart needle insertion force; (5) extraction force; (6) fatigue resistance; (7) compatibility with pacemakers; (8) lead pacing impedence; and (9) lead sensing impedence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 1 2001

Mr. Brian J. Young
Sr. Regulatory Affairs Manager
Weck Closure Systems
One Weck Drive, P.O. Box 12600
Research Triangle Park, N.C. 27709

Re: K011660
Trade Name: Weck Temporary Pacing Wires
Regulation Number: 21 CFR 870.3680
Regulatory Class: Class II (two)
Product Code: 74 LDF
Dated: May 25, 2001
Received: May 29, 2001

Dear Mr. Young:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

6 Statement of indications for use

510(k) Number (if assigned): K011660
Device Name: Weck Cardiac Pacing Wires

INDICATIONS FOR USE

Weck Cardiac Pacing Wires are intended for use in temporary cardiac pacing following cardiac surgery in adult and pediatric patients.

Concurrence of CDRH, Office of Device Evaluation (ODE)

K011660

Division of Cardiovascular & Respiratory Devices
510(k) Number

Prescription Use ✓
(Per 21 CFR 801.109)